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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,981	11/18/2003	Lars Andersson	4448-3	3661
23117	7590	06/02/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/714,981

Applicant(s)

ANDERSSON ET AL.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/18/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### ***Specification***

The disclosure is objected to because of the following informalities: page 1, lines 1 and 2 and page 3, lines 15 and 16 should be changed to remove the references to the claims, as the claims as originally filed may not correspond to the claims as allowed.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Claim Objections***

Claims 1-28 are objected to because of the following informalities: the claims are replete with foreign spelling version of English words. More specifically, the examiner has provided additional comments directed to claims 6, 10, 15.

Claim 6 as worded, (ie is designed as a graduated scale) would be better reworded as "marker forms a graduated scale pattern along a predetermined direction of the barrier:

Claim 10 the listed materials should be in Markush format.

Claim 15 should define "inside" as a surface or inner surface or surface intended to face the organ tissue. The verb "is" should be inserted before "arranged".

. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9, 13, 17, 19-21, 23, 27 and 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, the recitation of "or similar" is indefinite. The metes and bounds of the claims cannot be ascertained since it is not clear what other devices would be "similar" to a scapel.

Claim 9 is indefinite. It is not clear if the material is inert or is degradable?

Claim 13, there is no antecedent support for "cut resitant non-metallic fibre".

Claim 17 as worded is indefinite. The claims fails to set forth language that positively set forth the features of the claim. There is no support for "the butting edges. The "means of attachment" is not positively claimed.

Claims 17 and 19-21,23,27 and 28 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 25 as written contains improper alternative expression. The barrier is defined as an insulator or has properties provided with a degree of insulation. The two forms as claimed are not equivalent.

Claim 27 as worded is indefinite. The claim should positively set forth the materials (ie the the material characteristic appears in the preamble) in the body of the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1,2,4,5,9,11,14,15,27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (4202349).**

Claims 1 and 2, see the radiopaque discs of Jones. See indicia markings 17.

Claims 4,5,9 and 11, see column 3, lines 25-45.

Claim 14, as broadly worded the marker of Jones is a hard and rigid jacket.

(Note, the term jacket does not limit the same to any specific structure.)

Claim 15, see suture 24.

Claim 27, as broadly worded the marker of Jones is a synthetic implant with the characteristics as set forth in claim 1.

**Claims 1,4-12,14-24,27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shifrin et al (5476471).**

Shifrin et al discloses a device for correction of vascular junctions. Shifrin, et al uses fibers 11 embedded in the biocompatible coating. The fibers are shown as being spaced apart and extending in a direction along the axis of the device as broadly claimed. The fibers are metallic and are therefor radiopaque and thus meets the limitations of the claims.

Claim 4, see column 3, lines 14+ of Shifrin et al.

Claims 5,6,7,8,9, see column 3, lines 21+ and column 5, lines 1-13 of Shifrin, et al.

Claims 10 and 11, see column 4, lines 63 of Shifrin et al.

Claim 12, see column 5, lines 1-13 of Shifrin et al.

Claim 14, see device of Shifrin et al.

Claims 15 and 16, see figures 1 and 5.

Claims 17, 18, see bands 16 and 17 with fastening means 19 and 20.

Claims 19 and 20, see element 15 of Shifrin et al.

Claim 21 see elements 15-17 of Shifrin et al.

Claim 22 see fastening means 19 and 20.

Claim 23 see figures 1 and 5.

Claim 24, see figure 3.

Claims 27 and 28, see device of Shifrin et al.

**Claims 1, 9-11, 13, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lombardi, et al (5824042).**

Lombardi, et al discloses a vascular implant including non-metallic fibers that is coated with silicone. The device is secured at a tissue site and provides means for the surgeon to locate the device in vivo.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-4,9-12,14-24,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shifrin et al (5476471) in view of Neizs et al (6652450).**

Shifrin et al discloses a device for correction of vascular junctions. Shifrin, et al fails to disclose the use of a visual marker as a means for providing the surgeon with the ability to align, identify and properly place the device at the intended site. Neizs et al teaches means for providing visual indicator to assist the surgeon to properly align, identify and place the device at the intended site. To provide the device of Shifrin, et al with identifying means similar to that as taught by Neizs, et al to aid the surgeon in properly placing the device at the intended site would have been obvious to one with ordinary skill in the art.

Claims 2 and 3, see column 15, lines 8+ of Neizs et al.

Claim 4, see column 3, lines 14+ of Shifrin et al.

Claims 5,6,7,8,9, see column 3, lines 21+ and column 5, lines 1-13 of Shifrin, et al.

Claims 10 and 11, see column 4, lines 63 of Shifrin et al.

Claim 12, see column 5, lines 1-13 of Shifrin et al.

Claim 14, see device of Shifrin et al.

Claims 15 and 16, see figures 1 and 5.

Claims 17,18, see bands 16 and 17 with fastening means 19 and 20.

Claims 19 and 20, see element 15 of Shifrin et al.



Claim 21 see elements 15-17 of Shifrin et al.

Claim 22 see fastening means 19 and 20.

Claim 23 see figures 1 and 5.


Claim 24, see figure 3.

Claims 27 and 28, see device of Shifrin et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
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DJI

MAY 28, 2004